

**REMARKS**

Claims 40-59 are presently pending in the case. Claims 1-39 and 60 have been cancelled hereby without prejudice or disclaimer, Applicant reserving the right to pursue the claims in one or more continuing applications. Claims 40, 41, and 49 have been amended. The new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

**Claim rejections under 35 USC 112**

The Examiner rejected claim 50 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The language in claim 50 is supported in the description at least at page 6 lines 1-2. Accordingly, Applicant requests withdrawal of the rejection.

**Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 40-59 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,965,156 to Proffitt et al (hereafter Proffitt et al) in view of Published PCT Application WO 97/03649 to Staniforth et al (hereafter Staniforth et al) and in view of U.S. Patent 6,077,543 to Gordon et al (hereafter Gordon et al). The rejection is traversed.

Proffitt et al does not render claim 40, for example, unpatentable. Claim 40 is to a dry powder for delivery by inhalation to the lungs. In contrast, Proffitt et al discloses a liposomal polyene formulation that is hydrated so that it may be delivered intravenously to treat systemic fungal infections (see column 4 lines 20-54). Therefore, Proffitt et al does not render claim 40 unpatentable.

In addition, one of ordinary skill in the art would not have found it obvious to modify Proffitt in view of Staniforth and Gordon to change Proffitt et al's formulation to one that is a powder that is delivered to the lungs because doing so would go against the teachings of Proffitt et al. Proffitt et al teaches (1) a manner of making an injectable polyene formulation on a large scale and (2) the treatment of systemic fungal infections. Both of these teachings would be

destroyed by the Examiner's proposed modification. Accordingly, not only is there no motivation for one of ordinary skill in the art to make the proposed modification to Proffitt et al, but the person of ordinary skill would be taught away from doing so. For at least these reasons, Applicant requests withdrawal of the rejection of claim 40.

Claim 41 is also not rendered unpatentable by Proffitt et al. Claim 41 is to a dry powder made by a process comprising, inter alia, suspending a polyene antifungal compound in an aqueous solvent to form a suspension and spray drying the suspension. Proffitt et al teaches a polyene solution and does not teach a polyene suspension that is spray dried. The teachings of Staniforth et al and Gordon et al do not make up for the deficiencies of Proffitt, and one of ordinary skill in the art would not have found it obvious to modify the process of Proffitt et al based on these teachings, particularly in the absence of motivation to do so.

Independent claims 42 and 57 are not rendered unpatentable by the applied references, either. Claims 42 and 57 are to powder compositions suitable for oral inhalation to the lung comprising a therapeutically effective amount of a polyene antifungal compound. As discussed above, Proffitt et al does not disclose an inhaleable formulation and teaches away from a modification that would result in an inhaleable formulation. Therefore, claims 42 and 57 and the claims depending therefrom are not rendered unpatentable by Proffitt et al, Staniforth et al, and Gordon et al.

For at least these reasons, Applicant request withdrawal of the rejection of claims 40-59 and an indication of the allowability thereof.

#### **Information Disclosure Statement**

Applicant is filing under separate cover an information disclosure statement in compliance with MPEP section 609. Indication of consideration of the references provided is requested.

**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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Dated: 16 APR 2004

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